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EXAMINER: SIDBERRY, H

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This is a communication from the examiner in charge of your application.
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FOR RESTRICTION PURPOSES ONLY.

☑ This application has been examined ☑ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire ____ month(s), 30 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1-41 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☐ Claims _____ are rejected.
5. ☐ Claims _____ are objected to.
6. ☑ Claims 1-41 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EOK
05/25/99

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

Part III DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-9 and 34, drawn to proteins and pharmaceutical compositions, classified in Class 530, subclass 350+.

Group II. Claims 10-28, 32, 33, and 37, drawn to nucleic acids, vectors, methods of expressing nucleic acids, and unicellular host cells transformed with nucleic acids, classified in Class 536, subclass 23.5.

Group III. Claims 29-31, drawn to transgenic mammals, classified in Class 800, subclass 2.

Group IV. Claim 35, drawn to an antibody, classified in Class 424, subclass 130.1.

Group V. Claim 36, drawn to a method of administering a protein in vivo, classified in Class 514, subclass 2.

Group VI. Claim 38, drawn to a method for detecting DNA, classified in Class 435, subclass 6.

Group VII. Claims 39 and 40, drawn to a method of administering a protein in vitro, classified in Class 435, subclass 240.2.

Group VIII. Claim 41, drawn to a method of purifying a protein, classified in Class 436, subclass 512.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I-IV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the protein of Group I can be prepared by processes which are materially different from recombinant DNA expression of Group II, such as by chemical synthesis, or by isolation and purification from natural sources. Although the antibody of Group IV can be used to obtain the DNA of Group II, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The DNA of Group II can be used other than to make the protein of Group I, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group I can be used in materially different methods other than to make the antibody of Group IV, such as in therapeutic or diagnostic methods (e.g., in screening). Although the DNA of Group II can be used to make the transgenic mammals of Group III, the DNA can also be used to make materially different products, such as proteins.

Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct

for the following reasons: Groups V-VIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention V requires consideration of disease states, administration routes, and traditional drug therapy, which is not required by any of the other groups. Invention VI requires consideration of nucleic acid hybridization conditions, which is not required by any of the other groups. Invention VII requires consideration of cell culture conditions, which is not required by any of the other groups. Invention VIII requires consideration of antibody-antigen recognition and binding, which is not required by any of the other groups.

Inventions I and each of V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product can be used to raise antibodies which have a diagnostic utility.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the DNA of Invention II can be used to make proteins.

Inventions IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the antibodies of Invention IV can be used diagnostically, to locate thrombopoietin in situ without the additional purification steps required by Invention VIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Mr. Gary Parker on 02 June 1995 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Elizabeth C. Kemmerer, whose telephone number is (703) 308-2673. The Examiner can normally be reached on Tuesdays through Fridays from 7:30 a.m. to 5:00 p.m. The Examiner can also be reached on alternate Mondays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Garnette D. Draper, can be reached on (703) 308-4232. The fax number for this Art Unit is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

GARNETTE D. DRAPER
SUPERVISORY PRIMARY EXAMINER
GROUP 1800

Elizabeth C. Kemmerer, Ph.D.
June 2, 1995